AMERICAN ASSOCIATION OF BLOOD BANKS

STATEMENT OF THE AMERICAN ASSOCIATION OF BLOOD BANKS BEFORE THE BLOOD PRODUCTS ADVISORY COMMITTEE

Blood Bags for Diversion of the Initial Collection

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The American Association of Blood Banks (AABB) is the professional society for over 8,000 individuals involved in blood banking and transfusion medicine and represents roughly 2,000 institutional members, including community and Red Cross blood collection centers, hospital based blood banks, and transfusion services as they collect, process, distribute, and transfuse blood and blood components and hematopoietic stem cells. Our members are responsible for virtually all of the blood collected and more than 80 percent of the blood transfused in this country. For over 50 years, the AABB's highest priority has been to maintain and enhance the safety and availability of the nation's blood supply.

The AABB appreciates this opportunity to provide comment to the Blood Products Advisory Committee (BPAC).The frequency of transfusion associated bacterial sepsis is greater than that of any of the transfusion transmitted viruses currently tested for in the United States. Measures of the incidence of transfusion associated bacterial sepsis vary according to the method(s) employed for detection. Large variations are seen between institutions. Estimates include 1 in 1,500 units of whole blood-derived platelets with positive cultures [(1)], 1 in 15,000 donor exposures from whole blood-derived or apheresis platelets implicated with clinical signs of sepsis in a surveillance hospital study [(2)], 1 in 3,900,000 red cells, 1 in 116,000 apheresis platelets and 1 in 93,000 units of whole blood-derived platelets confirmed as causing clinical septic reactions in a national study using voluntary reporting [(3)], and, in the same study, 1 in 5,200,000 red cells, 1 in 260,000 apheresis platelets, and 1 in 740,000 units of whole blood-derived platelets causing mortality. Transfusion associated bacterial sepsis represents the most common cause of death from infectious diseases reported to the FDA, with 46 of 277 (16.6%) of all reported fatalities between 1990 to 1998 attributed to sepsis [(4)]. Among investigators of transfusion associated bacterial sepsis, there is general agreement that under-recognition and under-reporting of septic episodes is common. Several laboratory and clinical studies suggest that removing the first aliquot of whole blood via a diversion system will reduce the load and contamination rate of skin organisms [(5-9)]. The diverted blood can be utilized for viral testing and will prevent the unnecessary destruction of some whole blood units when samples cannot be collected at the end of the current procedure. All US bag manufacturers have worked on container designs for diversion systems. From an operational perspective, it is important that the design of these diversion systems be acceptable to blood providing organizations.

The AABB supports the encouragement of bag manufacturers and blood collection organizations to develop, validate and implement systems to divert the initial aliquot of donor blood to reduce the bacterial burden inoculated into blood and components.

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